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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 08/588,637
Filing Date: January 19, 1996
Appellant(s): BARBOUR ET AL.

Thomas J. Kowalski
For Appellant

SECOND SUPPLEMENTAL EXAMINER'S ANSWER

This is in response to applicants' Reply to Supplemental Examiner's Answer, received 26 July 2004

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

The rejection of claims 1-4,6-10, 12, and 13 under the judicially creatd doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U. S. Patent Number 5,688,512 in view of Bergstrom et al (U.S. Patent Number 5,523,089) is hereby withdrawn.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1-4, 6-10, 12, and 13 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

5,688,512	BERGSTROM et al	11-1997
5,523,089	BERGSTROM et al	6-1996

Cohen, S.N. "Immunization", in, Basic and Clinical Immunology, 3rd E., H.H. Fudenberg, D.P. Stites, J.L. Caldwell, J.V. Wells, eds., Lange Medical Publications, Los Altros, CA. (1980), pp. 708-721.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6-10, 12, and 13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of U.S. Patent No. 5,688,512 in view of Cohen.

Independent claim 1 is drawn to a method for inducing an immunological response in a mammalian host susceptible to Lyme disease or *Borrelia burgdorferi* infection comprising mucossally administering a composition comprising substantially pure outer surface protein A (OspA) and a carrier or diluent. The dependent claims 2-4, 6-10, 12, and 13 are further drawn to the type of OspA (recombinant, lipidated), how it is administered (orally or generally mucosal), and the choice of a carrier/diluent.

Claim 2 of U.S. Patent No. 5,688,512 depends from independent claim 1. Therefore, claim 2 is drawn to "A method of inducing a protective immunological response against *Borrelia burgdorferi* in an animal or human susceptible to Lyme disease comprising administering a vaccine comprising substantially pure OspA, and an immunologically acceptable carrier or vehicle to the animal or human in an amount effective for inducing the protective immunological response."

The recitation in claim 2 of U.S. Pat. No. 5,688,512 of "comprising administering a vaccine comprising substantially pure OspA" encompasses any route of administration, e.g., mucosal, intramuscular, subcutaneous, etc. Mucosally administrating the composition is but one type of administration. Cohen is a chapter from a textbook, utilized by the medical teaching profession, to discuss various vaccines and various routes of administration with mucosal administration merely one route of several.

Thus, since the field of immunization as evidenced by the Cohen reference recognized mucosal administration of vaccines as but one of several appropriate routes of administration, it would have been obvious to one of ordinary skill in the art at the time the invention was made that mucosal/oral administration of the claimed composition was an obvious variant of the many routes of administration available.

(11) Response to Argument

In Appellants Appeal Brief, Appellants argue that nothing in claim 2 of U.S. Pat. No. 5,688,512 or Cohen directs the skilled artisan to mucosally or orally administer the OspA of the instant claims and that neither reference provides motivation to modify the subject matter thereof to arrive at the present invention. Claim 2 administration can be by any route, but no particular route of administration is specified. Therefore, there is nothing in the disclosure of claim 2 that teaches or suggest the particular mucosal administration. Appellants argue that the Examiner failed to demonstrate why one should select oral or mucosal administration from all of the ways one can administer OspA based only upon the text of claim 2.

As appellants admit, claim 2 is directed to administration of OspA by any route, i.e., encompassing all routes, two of which are oral and mucosal. Cohen teaches various administration routes for effective immune response induction depending upon the organism being used, including mucosal/oral administration. Thus, one of skill in the art would have been motivated to modify the subject matter of claim 2, i.e., administration of OspA by **any/all** route(s), to utilize one of the effective routes taught by Cohen, either mucosal or oral.

Appellants argue that claim 2 of U.S. Pat. No. 5,688,512 requires protective immunity whereas the instantly rejected claim may result in protective immunity, but need not result in protective immunity.

As appellants admit in their argument in the Appeal Brief, the scope of both the instant claims and claim 2 comprises protective immunity. Thus, the instant claims are obvious variants of claim 2.

Appellants argue that claim 2 of U.S. Pat. No. 5,688,512 does not teach or suggest administration of lipidated OspA as recited in instant claims 2-4, 6, and 8-10, but only generic OspA.

According to M.P.E.P. '804, section **II.B**.1, paragraphs 6 and 7, determination of whether an invention of defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. However, the specification can be utilized as a dictionary in order to determine the meaning of a term in the patent. In addition, those portions of the specification which provide support for the patent claim may also be examined and considered when determining whether a claim in an application defines an obvious variation of an invention claimed in the patent.

Thus, to determine the support and definition concerning the recitation in claim 2 of U.S. Pat. No. 5,688,512 for "administering the vaccine of claim 1 to the animal or human in an amount effective for inducing the proective immunological response", one utilizes the specification. Specifically, column 18, lines 30-38 recite:

> "Any immunization route which may be contemplated or shown to produce an appropriate immune response can be employed in accordance with the principle of the present invention. Suitable administration forms of the vaccine of the invention are oral administration forms, e.g. tablets, granules or capsules, subcutaneous, intracutaneous or intramuscular administration forms or forms suitable for nasal or rectal administration."

Thus, the definition and support for patentability of claim 2 encompasses oral and mucosal (rectal) administration.

Likewise, patented claim 2 encompasses the administration of **any/all** forms of OspA of which lipidated OspA is but one obvious variant encompassed by the scope of the claims.

Claim 2 is directed to administration of OspA in any Aacceptable carrier or vehicle@ which encompasses **any/all** forms of administration, including solutions, suspensions, emulsions, syrups, elixirs, capsules, tablets, hard-candy-like preparations, or solid food items. The choice of a particular carrier or vehicle would be an obvious variant for one skilled in the art of immunization based upon that skilled artisan's experience in the field.

Appellants argue in their Reply Brief that the Examiner provides no citations for his characterizations of and extrapolations from Cohen et al and thus the rejetion is fatally flawed and must be vacated. Appellants argue in their Reply Brief that the Examiner's characterizations of and extrapolations from Cohen et al are baseless and therefore the rejection must fall and that the appellants do not see in Cohen et al "various routes of administration with mucosal administration merely one route of several".

The examiner utilized Cohen et al as a teaching reference, *in toto*, to indicate and provide the necessary motivation/incentive for utilizing many different modes of administration. The actual choice of the mode of administration would be decided upon by one of skill in the art, based upon the teachings of Cohen et al which, *in toto*, provides the guidance for the person of skill in the art.

Appellants argue in their Reply Brief that the Examiner fails to show why one would be motivated to modify U.S. Pat. No. 5,688,512, claim 2, for oral or mucosal administration or for any of the other recitations of the claims which do not stand or fall together.

The motivation for the modification of claim 2 was put forth in the original rejection and the Examiner's answer, based upon the actual claim and the basis of definition for administration route. The specification of U.S. Pat. No. 5,688,512, defines immunization route as any "suitable" administration route such as "oral administration" or "nasal or rectal administration". Each of the individually rejected claims are addressed by this definition of immunization route.

Appellants argue in their Reply Brief that the Examiner's reliance on the text of U.S. Pat. No. 5,688,512 in the Examiner's Answer is tantamount to a new rejection in the Examiner's Answer, and thus the rejection must be vacated and that the Examiner's reliance on the text of U.S. Pat. No. 5,688,512 is improper and based on a misunderstanding of the claims of U.S. Pat. No. 5,688,512 and their prosecution. Appellants argue in the Reply Brief that the M.P.E.P. requires consideration of indicia of nonobviousness and that the Examiner has failed to consider such evidence.

Appellants argue that in their Reply to Supplemental Examiner's Answer that the Supplemental Examiner's Answer is merely a rehash of the Examiner's Answer and fails to comply with the directions in the Remand "to prepare a substantive response to each point contained in the Reply Brief, taking into account the exhibits".

Concerning the issue that the Supplemental Examiner's Answer is silent as to the Exhibits to the Reply Brief.

Exhibit A = (unpublished) Ex parte Gambogi. Applicants Reply Brief mentions this reference to support their argument that the examiner has not referred to specific portions of Cohen. Applicants are directed to the first Office Action, mailed 22May2000, which specifically cites Table 43-3, see discussion of Cohen below.

Exhibit B = cited Cohen reference. Applicants merely state that this Exhibit B, was attached in case Applicants and Examiner are working from different documents with respect to that which has been cited as Cohen. This exhibit was provided by Applicants "for the convenience of the Board". The reference is specifically discussed in all preceding Office Actions, as well as the Supplemental Examiner's Answer.

Exhibit C = FDA panel backs Lyme disease vaccine. Applicants state that Ex. C. is provided for the convenience of the Board to take notice of a known fact that is also stated in the present application (see footnote 4), and in their Reply Brief that, based upon this cited reference, judicial notice be taken of the fact that commercially available Lyme Disease vaccines are and were administered by injection. While the examiner did not specifically note Ex. C, the entire discussion of routes of administration of vaccines was based upon historical Lyme disease vaccination, and specifically upon col. 18, lines 30-38 of U.S. Pat. No. 5,688,512, which directs one of ordinary skill in the art that any immunization route may be contemplated or shown to produce an appropriate immune response can be employed in accordance with the principle of the present invention.

Concerning the issue that the Supplemental Examiner's Answer does not address many portions of the Reply Brief, pages 3-9 and 12-13.

While the examiner disagrees with Applicants' view that the discussion of the applicability of the references does not address many portions of the Reply Brief, the examiner requests which portions Applicants' deem "many portions".

Pages 3-9 of Applicants' Reply Brief discuss: 1) definition of the claim subject, mucosal/oral administration of various forms of OspA, and adjuvants, 2) discussion that Applicants' did not see in Cohen "various routes of administration with mucosal administration merely one route of several", 3) how the examiner failed to show motivation for modification of U.S. Pat. No. 5,688,512, and 4) OspA as a protein.

The examiner discussed in both the Examiner's Answer and the Supplemental Examiner's Answer, administration routes, forms of OspA, acceptable carriers or vehicles, and motivations for modifying Pat. No. 5,688,512.

Concerning the issue that the Supplemental Examiner's Answer fails to cite any portion of Cohen.

The entire reference is to be taken for the discussion of the rejection, even though there was a specific cited portion of Cohen was given to Applicants in the first Office Action, mailed 22May2000, which states on page 4 of the Office Action, "Cohen---------teaches various routes of administering vaccines such as subcutaneous, intradermal, intramuscular and oral. (see especially Table 43-3)." Subsequent explanations by the examiner stated that Cohen, as a whole, cited Cohen reference is directed to the field of Immunization, particularly the modes of immunization, types of immunization, and the benefits and hazards of immmunization. Thus, consideration of the entire reference teachings indicate that oral/mucosal administration of the instantly claimed composition was only an obvious variant of the many routs of administration available.

Concerning the issue that the Supplemental Examiner's Answer fails to substantively respond to each of Applicants' arguments for the separate patentability of the claims.

The examiner did address the arguments concerning Applicants' recitation concerning the limitations of the various claims, e.g., adjuvants (claim 6), oral administration (claims 3, 4, 6, 9, 12, and 13), mucosal administration of lipidated rOspA (claims 2 and 8) and oral administration of lipidated rOspA (claim 9). While the specific claims were not elucidated, the limitations contained within each claim were discussed in light of the cited references.

As stated in the Examiner's Answer, a reliance on text is permissible for the defining of terms in the claims. Thus, the reliance on the text is not tantamount to a new rejection, but merely to provide guidance and definition for the terminology of the claimed invention. While the examiner did consider the prosecution of the patent in question and the experience of the prior examiner, the examination the instant application was performed based upon the support and specification of the instant application and the rules and regulations of the U.S. PTO. The examiner did consider indicia of obviousness and nonobviousness in determining the patentability of the instant application's claims.

Thus, for the reasons put forth above, appellants' arguments that each of the rejected claims is directed to a subgenus or species of OspA, route of administration, level of immunization, or carriers, distinct from claim 2 of U.S. Pat. No. 5,688,512, are not found persuasive and it is believed that the rejections should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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September 30, 2005

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